

PATENT / DOCKET NO.: 10287.39
CUSTOMER NO.: 27683

II. Amendments to the Claims

In compliance with the Revised Amendment Format, the text of all claims under examination is submitted, and the status of each is identified. This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

1. - 7. (Canceled)

8. (Previously presented) A labeled complex according to any one of claim 35 through claim 37, wherein said first and second labeled substances are selected from the group consisting of a fluorescent substance, a mineral phosphate, a luminescent substance and a chemiluminescent substance.

9. (Previously presented) A labeled complex according to claim 8, wherein the first and second labeled substances are luminescent and can be discriminated by a method selected from the group consisting of excitation wavelength, emission wavelength, emission intensity, degree of emission polarization, emission phase and emission lifetime.

10. (Previously presented) A labeled complex according to claim 9, wherein said carrier is bonded to the target receptor by an avidin, biotin bond.

11. (Previously presented) A labeled complex according to any one of claim 35 through claim 37, wherein said carrier is a magnetic particle, which can be controlled remotely.

12.- 34. (Canceled)

35. (Currently Amended) A labeled complex, comprising:
a carrier particle selected from the group consisting of a magnetic particle, charged particle, dielectric, chemotactic microorganism, synthetic resin bead, latex particle, glass bead, gel substance, and a metallic particle;

a number of target receptors of length up to 10 microns ~~1mm~~, each receptor having a first end and a second end,

wherein the first end of each receptor is bonded with said carrier particle,

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wherein said target receptors are single-stranded nucleic acids of predetermined base sequence,
and
wherein said target receptors bonded with a single carrier particle have the same or different base sequences;
and
at least a first type and a second type of labeled substance, each labeled substance bonded to a fraction of the number of target receptors at the second end of each receptor, thereby forming a labeled complex having a predetermined molar ratio of the types of labeled substances;
wherein the number and length of target receptors bonded to said carrier particle is such that a major influence by energy movement or quenching among the labeled substances does not occur, thereby enhancing discrimination by stable emission.

36. (Currently Amended) A labeled complex, comprising:
a carrier particle selected from the group consisting of a magnetic particle, charged particle, dielectric, chemotactic microorganism, synthetic resin bead, latex particle, glass bead, gel substance, and a metallic particle;
a number of target receptors of length up to 10 microns ~~1 mm~~, wherein said target receptors are double stranded nucleic acids of predetermined base sequence, each double stranded nucleic acid having a first single strand and a second single strand, each single strand having a first and a second end, wherein the target receptor has a first end of a first single strand bonded with said carrier, and wherein said target receptors bonded with a single carrier particle have the same or different base sequences;
and
at least a first type and a second type of labeled substance, each labeled substance bonded to a fraction of the number of target receptors at the second end of a second single strand, thereby forming a labeled complex having a predetermined molar ratio of the types of labeled substances;
wherein the number and length of target receptors bonded to said carrier particle is such that a major influence by energy movement or quenching among the labeled substances does not occur, thereby enhancing discrimination by stable emission.

37. (Currently Amended) A labeled complex, comprising:
a carrier particle selected from the group consisting of a magnetic particle, charged particle, dielectric, chemotactic microorganism, synthetic resin bead, latex particle, glass bead, gel substance, and a metallic particle;

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a number of target receptors of length up to 10 microns ~~1mm~~, wherein said target receptors are double stranded nucleic acids having a predetermined base sequence, each double stranded nucleic acid having a first single strand and a second single strand, each single strand having a first and a second end, wherein the target receptor has a second end of a first single strand bonded with said carrier, wherein said target receptors bonded with a single carrier particle have the same or different base sequences;

and

at least a first type and a second type of labeled substance, each labeled substance bonded to a fraction of the number of target receptors at the first end of a first single strand, thereby forming a labeled complex having a predetermined molar ratio of the types of labeled substances;

wherein the number and length of target receptors bonded to said carrier particle is such that a major influence by energy movement or quenching among the labeled substances does not occur, thereby enhancing discrimination by stable emission.

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III. Examiner Interview Summary

In a telephone conversation of January 26, 2004 between Examiner Sisson and Gloria L. Norberg, Examiner Sisson clarified the Advisory Action rejection as applying to all claims, not just the claims to a single stranded embodiment. The receptor length of 1mm was believed by the Examiner to apply to the particle and the receptor together, and was believed too long for describing the length of the receptor. The Examiner stated a preference for claim language to a specific number of nucleobases as the receptor length, or acceptable functional language as to the receptor length.

Applicants' representative appreciates the courtesy of the examiner in returning her telephone call and clarifying the rejection.

IV. Remarks

A. Status of the Application

Claims 35-37 are amended. Claims 8-11 and 35-37 are pending.

B. Rejections of Claims 8-11 and 35-37 under 35 U.S.C. §112, First Paragraph **Office Action**

Claims 8-11 and 35-37 were rejected in the Final Office Action for introduction of new matter. In particular, Claims 35-37 were rejected for the following: "where target receptors have a length of up to 1mm," "a labeled complex having a predetermined molar ratio of the labeled substances," and "number and length of target receptors."

Claim 35 was rejected in the Final Office Action for "where single-stranded target receptors have a predetermined base sequence."

The Advisory Action states that the response filed December 29, 2003 does not place the application in condition for allowance because: a review of page 9 and of original claim 3 fails to find support for where the "target receptors," which "are single-stranded nucleic acids of a predetermined base sequence are "of length up to 1mm." Support is cited as present for where the combination of "target receptor, which is bonded with the carrier on a part thereof, and bonded with the labeled substance on the other part thereof, is formed in a slender shape" which can be of a length of up to 1mm. The combination of elements was cited as not teaching that the "target receptor" alone, which must be of a predetermined sequence and be single stranded nucleic acid, be of that length.

The Communication mailed February 27, 2004 stated that removal of the "length up to 1mm" language would remove the new matter rejection but would raise a new issue of total reliance on functional language as it relates to satisfaction of the written description requirement.

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Response

The claims have been amended to recite the length of the target receptor as up to 10 microns. Support for up to 10 microns for the length of the target receptor is found in the specification at page 8, line 28, to page 9, line 9, specifically at line 9. Said lines state:

..., the target receptor, ..., is formed in a slender shape ... (page 9, line 3). The size of the "slender shape" is not expressly defined (page 9, line 5). ... For example, the form is as long as or sufficiently longer than the particle size (page 9, lines 7-8), for example, about 10 times as long as the particle size, for example, about 10 μ m (page 9, lines 8-9).

Support for the remaining objectionable claim language of the independent claims is found in the specification and originally filed claims as follows:

In the third aspect of the invention (begins on page 8, last line), the target receptor is formed in a slender shape (page 9, line 1-3). Further, the target receptor is alone referred to as being in a slender shape since the rest of the sentence is set off in phrases with commas. Therefore, the "slender shape" refers to the receptor only.

In the fifth aspect of the invention (begins on page 10, line 18), which refers to any one of the first through the fourth aspects of the invention, the target receptor has a predetermined double strand base sequence. Therefore, this aspect refers to the third aspect which describes the target receptor in a slender shape. Therefore, the receptor may be a double strand base sequence of predetermined sequence in a slender shape.

In the seventh aspect of the invention (begins on page 11, line 11), which refers to any one of the first through the fifth aspects of the invention, the target receptor is a single strand nucleic acid. Therefore, this aspect refers to the fifth aspect which describes the receptor as double stranded, and the seventh aspect further describes the target receptor as denatured to a single strand. This aspect still has a predetermined base sequence and a slender shape.

Therefore, the seventh aspect of the invention describes a target receptor as having a slender shape, as being a single strand nucleic acid, and having a predetermined base sequence.

With regard to the length of a "slender shape," at page 9 and in Claim 3 as originally filed, the target receptor is cited as formed in a slender shape (page 9, line 3). The size of the "slender shape" is not expressly defined (page 9, line 5), however, for example, the form is as long as or sufficiently longer than the particle size (page 9, lines 7-8), for example, about 10 times as long as the particle size, for example, about 10 μ m (page 9, lines 8-9).

At page 5, the particle size is cited as preferably of the order of about 0.1 μ m ~ about 1 mm (lines 11-13). Therefore, the target receptor may be from 0.1 μ m to about 10 mm. The Office Action of Feb. 12, 2003 requested that a limit be put on the length of immobilized polynucleotides. Since the value of 10

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microns is expressly stated in the specification, that value is selected as a limit on the length of target receptors.

The receptor, in a slender shape, functions as a spacer (page 9, lines 10-11). As supported by page 9, lines 10-23, the "slender shape" and, therefore, the length of the receptor is such that a major influence by energy movement or quenching among the labeled substances does not occur, thereby enhancing discrimination by stable emission, as stated in independent Claims 35-37. Lines 10-23 of page 9 are repeated here:

The reason why a slender shape is formed is to make it play a role as a spacer where, by attaching a labeled substance such as a luminescent material and the like on one end, compared with the case of attaching the labeled substance to a carrier such as a micro particle and the like, the space to the carrier and the space and distance between the labeled substances are expanded, and hence energy movement between the labeled substances and the occurrence of quenching are prevented, so that it guarantees more reliably the possibility of consistent discrimination of emissions and the like. According to the present invention, since a larger space can be obtained between the labeled substances compared with direct bonding to the carrier, interactions such as energy movement between the labeled substances, quenching (in the case of luminescent material), and the like are prevented, so that for example a number of substances, more than thousands and tens of thousands, can be discriminated consistently and with high accuracy.

Applicants believe that support for the claim language "length of the receptor is such that a major influence by energy movement or quenching among the labeled substances does not occur, thereby enhancing discrimination by stable emission" of Claims 35-37 is present as set forth above and that the cited phrase of said claims functionally defines the length of the receptor and that the present amendment satisfies any new issue regarding written description regarding the length of the target receptor. One of ordinary skill in the art, in light of the present disclosure, would be able to determine without undue experimentation the length of a receptor "such that a major influence by energy movement or quenching among the labeled substances does not occur, thereby enhancing discrimination by stable emission" and in light of the length of the target receptor as up to 10 microns.

Since the independent claims are supported by the specification as filed, claims dependent thereon also have support. Applicants respectfully request that the rejection of Claims 8-11 and 35-37 under 35 U.S.C. §112, first paragraph, be withdrawn for the reasons cited herein.

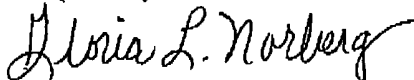
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C. Conclusion

It is believed that all matters set forth in the Final Office Action, the Advisory Action, and the Communication have been addressed. Further reconsideration and an early indication of the allowability of the pending claims are respectfully requested. Should the Examiner believe that an interview with Applicant's undersigned agent would expedite consideration of the pending claims, the Examiner is invited to call the undersigned agent at 512.867.8528.

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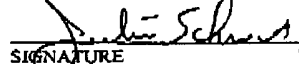
Respectfully submitted,


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